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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/18/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/888,959

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed July 11, 2003 is acknowledged. Claims 4-6 were canceled. Claims 18-20 were added.

Claims 1-3 and 7-20 are pending.

Claims 8-17, drawn to non-elected species, are withdrawn from consideration.

Claims 1-3, 7 and 18-20 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to the disclosure is withdrawn in view of the amendment to the specification deleting the embedded hyperlinks.

Claim Rejections Maintained:

4. The rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) as being anticipated by Robbins (Robbins, B.A. et al., Blood, 82(4): 1277-1287, 1993) is maintained for the reasons of record.

This rejection is applied to new claim 19.

Applicants' arguments have been carefully considered, but are unpersuasive. Applicants assert that Robbins teaches the claimed methods because Robbins fails to teach a method that establishes a pattern of presence or absence or level of CD antigens. However, Robbins does teach a pattern of CD expression for CLL (and also for HCL). Robbins teaches that for CLL

Art Unit: 1642

there is coexpression of CD11c with CD19, coexpression of CD25 with CD19, no expression of B-ly-7 and that all CLL cells are positive for CD5 (see pages 1280-1282). Robbins teaches that this pattern is distinct from HCL, in that CLL specimens exhibit only weak to moderate expression of CD11c or CD25 staining.

5. The rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) as being anticipated by Valet (Valet, G.K. et al, Cytometry, 20: 275-288, 1997) is maintained for the reasons of record. This rejection is applied to new claims 19 and 20.

Applicants' arguments have been carefully considered, but are unpersuasive. Applicants assert that Valet teaches the claimed methods because Valet fails to teach a method that establishes a pattern of presence or absence or level of CD antigens. However, Valet teaches patterns of CD expression that allow the discrimination between B-CLL, lymphoplasmacytoid immunocytoma and low-grade non-Hodgkin's lymphomas, and teaches that total antibody binding, antibody binding ratios and relative antibody surface density (all of these parameters read on establishing a pattern of "level" of CD antigens) is the most highly discriminant information (see abstract). Valet teaches the use of samples that are whole blood (see page 276, 1st col).

6. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Terstappen (U.S. Patent 5,234,816; issued August, 1993). This rejection is applied to new claim 19.

Applicant asserts that the method of Terstappen is two dimensional, whereas the method of the claimed inventions is multidimensional and therefore, Terstappen fails to disclose a

Art Unit: 1642

method that establishes a pattern of presence or absence or level of CD antigens. However, this is unpersuasive because the claims encompass methods where as few as one antibody is used, and also, while Terstappen's method may use pairs of antibodies, Terstappen discloses using 5 pairs of antibodies. Thus, Terstappen discloses methods for classifying leukemias comprising contacting samples with antibodies that bind to CD antigens (see, for example, col. 2, line 66 – col. 3, line 25) or with antibodies where at least one of the antibodies binds to an antigen from CLL (for example Terstappen teaches using an antibody to CD5). Thus, Terstappen discloses methods that are the same as that claimed.

7. The rejection of claims 1-3, and 7 under 35 U.S.C. 102(b) as being anticipated by Moreau (Moreau, E.J. et al, Am. J. Clin. Pathol., 108: 378-382, 1997), Matutes (Matutes, E. et al., Blood, 83(6):1558-1562, 1994) or Kurec (Kurec, A.S. et al, British J. Haematology, 81: 45-51, 1992) is maintained for the reasons of record. This rejection is applied to new claim 19.

Applicant argues that Moreau, Matutes and Kurec each fail to teach the claimed inventions because they do not teach a pattern of presence or absence or level of CD antigens. This is not found persuasive because, Moreau teaches a pattern of absence of CD38, presence of CD23, presence of CD5 and weak negative expression of CD22 in CLL patient samples (page 380, Table 4). Matutes teaches a pattern of CD expression in CLL (page 1560, Table 3). Kurec teaches a pattern of CD expression in CLL (page 49, 2nd col).

Art Unit: 1642

8. The rejection of claims 1-3, and 7 under 35 U.S.C. 103(a) as being unpatentable over Valet in view of Chang (U.S. Patent 4,591,570; issued May 27, 1986) is maintained for the reasons of record. This rejection is applied to new claims 18-20.

Claims 1-3, 7, and 18-20 may be interpreted as drawn to methods where the antibodies that are used are associated with a solid support. Applicant argues that the examiner has used improper hindsight in constructing the rejection of the claims as obvious over the prior art. This argument is not found persuasive because applicant fails to demonstrate that the examiner failed to point to motivation for combining the references, or to a teaching in the specification that is an element of the invention that may only be gleaned from the instant specification. The rejection is maintained because, as discussed in the previous Office action, Valet teaches a pattern of CD antigen expression as a method for identifying types of leukemia and because Chang teaches assays where the antibodies are attached to solid supports and Chang teaches the advantages of using antibodies arranged in such arrays (see col. 1, lines 32 – col. 2, line 12). Chang also teaches the use of polyclonal antibodies (col. 4, lines 1-3).

9. The rejection of claims 1-3, and 7 under 35 U.S.C. 103(a) as being unpatentable over Robbins (Robbins, B.A. et al., Blood, 82(4): 1277-1287, 1993) Terstappen (U.S. Patent 5,234,816; issued Aug. 1993), Moreau (Moreau, E.J. et al, Am. J. Clin. Pathol., 108: 378-382, 1997), Matutes (Matutes, E. et al., Blood, 83(6):1558-1562, 1994) or Kurec (Kurec, A.S. et al, British J. Haematology, 81: 45-51, 1992) in view of Chang (U.S. Patent 4,591,570; issued May 27, 1986) is maintained for the reasons of record. This rejection is applied to new claims 18 and 19.

Art Unit: 1642

Claims 1-3, 7, 18 and 19 may be interpreted as drawn to methods where the antibodies that are used are associated with a solid support. Applicant argues that the examiner has used improper hindsight in constructing the rejection of the claims as obvious over the prior art. This argument is not found persuasive because applicant fails to demonstrate that the examiner failed to point to motivation for combining the references, and because applicant failed to point to a teaching in the specification that is an element of the invention that may only be gleaned from the instant specification. The rejection is maintained because, as discussed in the previous Office action, as discussed above, any of Robbins, Terstappen, Moreau, Matutes, or Kurec teaches a pattern of CD antigen expression as a method for identifying types of leukemia and, because Chang teaches assays where the antibodies are attached to solid supports and, Chang teaches the advantages of using antibodies arranged in such arrays (see col. 1, lines 32 – col. 2, line 12). Chang also teaches the use of polyclonal antibodies (col. 4, lines 1-3).

New Grounds of Rejection:

10. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it recites a list that is supposed to be a list of CD antigens. However, the list includes elements that are not CD antigens.

11. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in

Art Unit: 1642

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the amendment to claim 3 introduces new matter into the specification.

The amendment to claim 3 adds elements to a list of CD antigens. Applicant has failed to specifically point to support for an array of antibodies that consists of the recited antigens in the list. Furthermore, a review of the specification demonstrates that applicants did not contemplate an array containing the listed antigens, as recited in amended claim 3, as an array of antigens. Thus, applicants were not in possession of the invention at the time the application was filed.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1642


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
November 5, 2003


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